General

Guideline Title

Mirabegron for treating symptoms of overactive bladder.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Mirabegron for treating symptoms of overactive bladder. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 52 p. (Technology appraisal guidance; no. 290).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Mirabegron is recommended as an option for treating the symptoms of overactive bladder (OAB) only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects.

People currently receiving mirabegron that is not recommended for them as described above should be able to continue treatment until they and their clinician consider it appropriate to stop.

Clinical Algorithm(s)

This guidance has been incorporated into the following NICE Pathways available from the National Institute for Health and Care Excellence (NICE) Web site:

- Lower Urinary Tract Symptoms in Men
- Urinary Incontinence in Women

Scope

Disease/Condition(s)

Overactive bladder (OAB)

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Urology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of mirabegron for treating symptoms of overactive bladder (OAB)

Target Population

Adults (≥18 years of age) with symptomatic overactive bladder (OAB)

Interventions and Practices Considered

Mirabegron

Major Outcomes Considered

- Clinical effectiveness
  - Urinary frequency
  - Frequency of urge urinary incontinence
  - Frequency of urgency episodes
  - Level of urgency
  - Nocturia
  - Health-related quality of life (HRQoL)
  - Adverse effects of treatment
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Searches

The manufacturer conducted two systematic reviews of the literature to identify relevant clinical data to inform on the efficacy and safety of mirabegron for the treatment of adults with symptoms of overactive bladder (OAB). One review was limited to randomised controlled trials (RCTs), and studies directly comparing mirabegron with the treatments of interest listed in the final scope issued by NICE. In addition, this literature was used to inform the mixed treatment comparison (MTC), where head-to-head RCTs proved to be insufficient. The second review was designed to identify non-RCT evidence on the efficacy and safety of mirabegron.

The manufacturer lists the databases and trial registers searched, conference proceedings that were hand searched, and the time spans of the searches. The manufacturer also searched reference lists of identified trials and systematic reviews. The literature was searched on 13th June 2012 for both the systematic review of RCTs and non-randomised studies.

The search terms included commonly used words to describe the disease, drug names and brand names for mirabegron and the comparators listed in the scope. It also included appropriate search terms for study design. The manufacturer did not specify a separate search strategy for identifying adverse events.

Due to time constraints, the ERG has been unable to validate fully the manufacturer's searches and verify the number of studies identified. However, the ERG considers the manufacturer's searches to be comprehensive and the search strategies used for each systematic review to be appropriate. In addition, the ERG is unaware of any relevant studies that have been missed by the manufacturer's search.

Inclusion/Exclusion Criteria

For both the systematic review for RCTs and non-randomised studies, two reviewers independently assessed identified references for inclusion/exclusion and any discrepancies were resolved by a third reviewer.

Inclusion and exclusion criteria and appropriate flow diagrams were provided for the literature searches for RCTs and non-randomised studies (see Appendix 1 of the ERG report [see the "Availability of Companion Documents" field]).

Direct Clinical Evidence

The inclusion/exclusion criteria of RCTs for direct comparisons and non-randomised studies predominantly aligned with the final scope. However, the ERG notes that the inclusion criteria relating to the intervention of interest, as stated by the manufacturer, included mirabegron or oxybutynin (including modified-release preparations) (see Appendix 1 of the ERG report [see the "Availability of Companion Documents" field]). No studies evaluating oxybutynin were included by the manufacturer as direct clinical evidence on the effects of mirabegron. In addition, the manufacturer's review excluded studies evaluating transdermal oxybutynin as a comparator. The manufacturer stated that the decision to exclude studies evaluating transdermal oxybutynin was based on the differences in placebo administration (i.e., placebo patch versus oral tablet). The ERG considers the exclusion of non-oral formulations of oxybutynin to be inappropriate.

No separate search was conducted to identify studies looking at the safety of mirabegron. However, the manufacturer presents safety data from all the trials for which they also presented direct clinical effectiveness data.

The manufacturer identified seven trials in the population of interest, which evaluated mirabegron at the anticipated licensed doses (50 mg [recommended dose], and 25 mg for those with hepatic or renal failure).

However, in the manufacturer's submission (MS), the direct clinical evidence is based on a pooled analysis of only three of the trials (SCORPIO,

ARIES, CAPRICORN), and the safety data are based on the long-term study TAURUS. The reasons provided by the manufacturer for not including the four remaining trials in the pooled analysis for the direct clinical evidence are listed in Table 2 of the ERG report (see the "Availability of Companion Documents" field).

The ERG considers the four excluded trials to be relevant to the decision problem that is the focus of this Single Technology Appraisal (STA). Therefore, these four trials are discussed throughout the report alongside the three trials included by the manufacturer in the pooled analysis of direct clinical evidence. The eligibility of inclusion of the four excluded trials is discussed in greater detail in the ERG report (see the "Availability of Companion Documents" field).

See Table 4 of the ERG report (see the "Availability of Companion Documents" field) for the patient inclusion criteria for the randomised controlled trials evaluating mirabegron.

Cost-Effectiveness

Summary and Critique of the Manufacturer's Review of Cost-Effectiveness Evidence

The manufacturer carried out a systematic review of the literature with the aim of identifying economic evaluations and costing studies considering treatments for OAB. Searches of the following databases: Medline, Embase, Medline (R) In-Process, EconLIT and National Health Service Economic Evaluation Database (NHS EED) were carried out on 26th November 2011; no date restrictions were applied to the search. The ERG notes that the search terms used were reasonable and both inclusion and exclusion criteria were explicitly stated. However, the ERG notes that the manufacturer did not supplement the database search with hand-searching of review bibliographies, conference abstracts or manufacturer's databases. Although, based on supplementary searches, the ERG considers it unlikely that any relevant publications were excluded.

The manufacturer's review identified seven costing studies and 16 economic evaluations. All of the identified economic evaluations considered currently available pharmaceutical interventions for OAB; however, none considered the cost-effectiveness of mirabegron. Table 41 of the ERG report summarises the economic evaluations identified by the manufacturer's systematic review (see the "Availability of Companion Documents" field).

See Section 5.1 of the ERG report for additional information (see the "Availability of Companion Documents" field).

Number of Source Documents

Clinical Effectiveness

- Seven randomised controlled trials (RCTs) were included.
- Forty studies meeting inclusion criteria for mixed treatment comparison were included.
- One non-randomised study was also included.

Cost-effectiveness

- Seven costing studies and 16 economic evaluations were identified. All of the identified economic evaluations considered currently available pharmaceutical interventions for overactive bladder (OAB); however, none considered the cost-effectiveness of mirabegron
- The manufacturer presented an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Quality Assessment

The manufacturer assessed the trials included in the direct clinical evidence and the mixed treatment comparison (MTC) against criteria adapted from guidance for undertaking reviews in health care issued by the Centre for Reviews and Dissemination, as provided in the NICE template for manufacturer/sponsor submission of evidence to the Single Technology Appraisal (STA) process.

Direct Clinical Evidence

The manufacturer's quality assessments for the randomised clinical trials (RCTs) informing the direct clinical evidence are summarised in Table 6 of the ERG report (see the "Availability of Companion Documents" field).

The ERG notes that the manufacturer's descriptions of how the quality issues were addressed in the studies were reproduced from the individual clinical study reports (CSRs), but the ERG considers that, in some cases, insufficient details were provided on the methods used to minimise bias and ensure methodological rigour. The manufacturer states that all seven trials were randomised. However, the ERG considers that, for some trials, it is unclear how the randomisation sequence was generated, and how the random allocation was concealed. All the trials were described as being adequately blinded. However, the ERG notes that the methods implemented to achieve and maintain blinding were not described. The ERG agrees with the manufacturer that the baseline characteristics of the treatment groups in the different trials were well balanced.

All seven trials based the primary efficacy analysis on the full analysis set (FAS) rather than an intention-to-treat (ITT) population. The FAS population comprised all randomised patients who took ≥1 dose of double-blind study drug and who had a micturition measurement in the baseline diary and ≥1 post-baseline visit diary with a micturition measurement. The manufacturer asserts that use of the FAS population is consistent with other overactive bladder (OAB) trials, and the ERG considers the use of the FAS population appropriate.

The manufacturer's quality assessment, with accompanying comments from the ERG, is presented in Appendix 5 of the ERG report (see the "Availability of Companion Documents" field).

Indirect Clinical Evidence

The manufacturer states that there are no doubts about the relevance of these trials when performing the MTC analyses. However, according to the manufacturer's quality assessment, a number of the studies had a high risk of bias for several of the quality questions, or it was unclear how the quality issues had been addressed. Due to time constraints, the ERG was unable to validate the quality assessment for each individual trial. However, based on the manufacturer's quality assessment of the trials, the ERG has concerns that it might be inappropriate to include all the identified trials in the MTC. Issues regarding the quality of the trials included in the MTC are discussed in more detail in Section 4.4 of the ERG report (see the "Availability of Companion Documents" field).

Description and Critique of Statistical Approach and Data Synthesis, Direct Clinical Evidence

Individual RCTs

The ERG considers the manufacturer's use of the FAS population to be appropriate and to be consistent with other studies of antimuscarinics. The ERG acknowledges the manufacturer's point that the ITT population was not reported across all trials of currently available antimuscarinics. The manufacturer performed sensitivity analysis on the primary outcome data from SCORPIO, ARIES, and CAPRICORN using the ITT population (urinary frequency and frequency of incontinence). The ITT population comprised all randomised patients who took ≥1 dose of double-blind study drug and who had a baseline diary with micturition measurements. Safety and adverse events were based on the safety analysis set (SAS), which was defined as all randomised patients who took ≥1 dose of double-blind study drug.

Meta-Analysis

The manufacturer did not perform a meta-analysis of the identified RCTs, with no rationale for this decision provided by the manufacturer. However, the manufacturer reported the results of a pre-specified pooled analysis of SCORPIO, ARIES, and CAPRICORN using the FAS populations, including subgroup analyses based on gender and previous treatment with antimuscarinics (i.e., yes versus no). The manufacturer pooled data for the placebo and mirabegron 50 mg treatment groups from the three RCTs; data from the mirabegron 25 mg treatment group in CAPRICORN were not pooled as CAPRICORN was the only study reported as direct clinical evidence evaluating mirabegron at this dose. Although the results of the manufacturer's pooled analysis augment the results for the individual trials on the clinical effectiveness of mirabegron compared with placebo, the ERG considers that the analysis does not fully inform the decision problem that is the focus of this STA as placebo is not a comparator of interest in the final scope. The ERG carried out a meta-analysis of data from RCTs evaluating mirabegron and tolterodine, which is listed as a comparator of interest; the results of the ERG's meta-analysis are described in Section 4.4.1 of the ERG report.

The pooled analysis involved a multiplicity adjustment based on the included trials. The outcomes were analysed using analysis of covariance (ANCOVA) with treatment group, gender and study as factors and baseline values as a covariate. Stratified rank ANCOVA was used for hypothesis testing. For each endpoint variable the stratified rank ANCOVA was performed for the pairwise comparisons of mirabegron 50 mg versus placebo. No statistical assessment of heterogeneity was performed on the pooled analysis. Subgroup analyses were performed based on gender, and previously treated versus treatment-naïve patients, in accordance with the NICE final scope.

Description and Critique of Statistical Approach and Data Synthesis, MTC

The manufacturer conducted a Bayesian MTC using a Markov Chain Monte Carlo (MCMC) simulation to estimate the relative efficacy and safety of mirabegron compared with all comparators listed in the final scope for this STA, and versus placebo.

For each population, a fixed effect and a random effect model were used with a non-informative prior distribution allowing for correlation between different arms within multi-arm studies. The model with the best fit, as assessed by the deviance information criterion (DIC), was selected (i.e., the model with the lowest DIC). Tolterodine 4 mg was selected as the reference treatment for analyses of efficacy outcomes, as this treatment was the comparator in the health economic model of mirabegron and was also the most widely reported active comparator in the trials included in the MTC. For the analyses of safety outcomes, tolterodine 4 mg was selected as the reference treatment.

See Section 4 of the ERG report for additional information (see the "Availability of Companion Documents" field).

Cost-Effectiveness

Summary and ERG Critique of the De Novo Economic Evaluation Submitted by the Manufacturer

In support of this STA, the manufacturer submitted four electronic versions of the Microsoft© EXCEL-based economic model, as follows:

- A primary base case model, based on efficacy data from SCORPIO which considered the comparison of mirabegron 50 mg with tolterodine extended release (ER) 4 mg
- A secondary base case model, based on efficacy data from the manufacturer's MTC, considering mirabegron 50 mg versus all comparators (except oxybutynin immediate response [IR] 10 mg) listed in the NICE scope
- A version of the secondary base case model including oxybutynin IR 10 mg
- A version of the secondary base case model including the impact of co-morbidity

The ERG considers the manufacturer's models to be generally well constructed and largely transparent. In addition, the ERG considers that disaggregating the submitted economic analyses into distinct versions of the model facilitated examination of each analysis.

NICE Reference Case Checklist

Tables 42 and 43 of the ERG report summarise the ERG's assessment of the manufacturer's economic evaluation against the NICE reference case and Philips checklists, respectively (see the "Availability of Companion Documents" field).

Model Structure

The manufacturer's *de novo* Markov model considered the costs and consequences of mirabegron versus currently available antimuscarinics for overactive bladder. The therapeutic management of patients (including complications), severity and progression of disease were assessed in a hypothetical cohort of OAB patients in monthly cycles over a 5 year time horizon. The model was constructed to assess costs and consequences from a societal or National Health Service (NHS) Payer perspective. However, in the manufacturer's submission, only results from an NHS payer perspective were reported. Costs and benefits were discounted at a rate of 3.5% per annum in line with NICE reference case.

The ERG considers that the structure of the manufacturer's model was reasonable and appropriately captured the consequences (costs and benefits) of treatments for OAB. However, the ERG notes that no rationale was provided for assuming that patients who fail on conservative antimuscarinic therapy would receive botulinum toxin, rather than other invasive procedures recommended by NICE. In addition, the ERG notes that a majority of parameters informing treatment discontinuation and switch were based on expert clinical opinion. Furthermore, the ERG notes that these values were estimated through open discussion, rather than through the use of elicitation techniques. Therefore, the ERG considers that this aspect of the manufacturer's model will be subject to additional parameter uncertainty.

See Sections 5 and 6 of the ERG report for more information on cost-effectiveness analysis (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The manufacturer's cost-effectiveness evidence consisted of a systematic literature review and a de novo Markov model. The Committee noted the Evidence Review Group's (ERG's) comment that the manufacturer's model was accurate and transparent.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee noted the ERG's concerns related to some of the costs in the model and assumptions of discontinuation.

The Committee acknowledged there were no real-life data on persistence with mirabegron, and that data from the trials were unlikely to be representative of the persistence rates in clinical practice because in the trials, patients were actively encouraged to continue taking the drug for the entire trial duration.

It observed that this analysis relied on the effectiveness results from the manufacturer's mixed treatment comparison (MTC) and that, for technical reasons, it had not been possible for the results from the ERG's MTC to be incorporated into the ERG's economic analyses.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values

The manufacturer used utility values derived from EQ-5D (EuroQol 5 dimensions questionnaire) scores collected in SCORPIO for its primary base case. The manufacturer performed sensitivity analyses based on the overactive bladder questionnaire (OAB-q) and EQ-5D scores collected in SCORPIO, ARIES and CAPRICORN. The ERG thought that SCORPIO utility data would be likely to be biased against the more effective treatment, as would the use of EQ-5D rather than OAB-q data.

Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

No potential health-related benefits have been identified that were not included in the model.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost-Effective?

The Committee considered treatment group by age, sex and by treatment status (pre-treated or treatment-naive), but concluded there was no evidence for differential clinical effectiveness and therefore no evidence for differential cost-effectiveness in these subgroups.

What Are the Key Drivers of Cost-Effectiveness?

The key driver of cost-effectiveness was the assumption around the persistence rates.

Most Likely Cost-Effectiveness Estimate (Given as an Incremental Cost-Effectiveness Ratio [ICER])

The Committee concluded that, because the base-case ICER for mirabegron against tolterodine tartrate 4 mg was £5270 per QALY gained in the ERG's sensitivity analysis, changes to the modelling of adverse events was unlikely to result in an ICER that made mirabegron cost ineffective against tolterodine tartrate 4 mg. The Committee concluded that the effectiveness of mirabegron is similar to that of antimuscarinic drugs and it appears to have a different side-effect profile. However, there is uncertainty about the differences in costs and effects between drugs and the ICERs are therefore unstable.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups

- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer and a review of this submission by the Evidence Review Group (ERG). For clinical effectiveness, three randomised controlled trials were the main source of evidence. For cost-effectiveness, the manufacturer's model and the additional economic analysis undertaken by the ERG were considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of mirabegron for treating symptoms of overactive bladder (OAB)

Potential Harms

The summary of product characteristics lists the following adverse reactions for mirabegron: urinary tract infection, tachycardia, vaginal infection, cystitis, palpitation, atrial fibrillation, dyspepsia, gastritis, urticaria, rash, rash macular, rash popular, pruritus, joint swelling, vulvovaginal pruritis, increased blood pressure, increased gamma-glutamyl transpeptidase, increased aspartate aminotransferase, increased alanine aminotransferase, eyelid oedema, lip oedema, leukocytoclastic vasculitis and purpura (rash).

For full details of adverse reactions and contraindications, see the summary of product characteristics available at http://emc.medicines.org.uk/.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that if a patient has overactive bladder and the doctor responsible for their care thinks that mirabegron is the right treatment, it should be available for use in line with NICE's recommendations.
- NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on the NICE website (http://guidance.nice.org.uk/TA290).
    - Costing template and report to estimate the national and local savings and costs associated with implementation.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Mirabegron for treating symptoms of overactive bladder. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 52 p. (Technology appraisal guidance; no. 290).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Jun

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Dr Jane Adam (*Chair*), Department of Diagnostic Radiology, St George's Hospital, London; Professor Iain Squire (*Vice-Chair*), Consultant Physician, University Hospitals of Leicester; Professor Thanos Athanasiou, Professor of Cardiovascular Sciences and Cardiac Surgery, Imperial College London, Consultant, Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust; Dr Jeremy Braybrooke, Consultant Medical Oncologist, University Hospitals Bristol NHS Foundation Trust; Dr Gerardine Bryant, General Practitioner, Swadlincote, Derbyshire; Dr Fiona Duncan, Clinical Nurse Specialist, Anaesthetic Department, Blackpool Victoria Hospital; Mr Andrew England, Lecturer in Medical Imaging, NIHR Fellow, University of Liverpool; Professor Jonathan Grigg, Professor of Paediatric Respiratory and Environmental Medicine, Barts and the London School of Medicine and Dentistry, Queen Mary University London; Dr Brian Hawkins, Chief Pharmacist, Cwm Taf Health Board, South Wales; Dr Peter Heywood, Consultant Neurologist, Frenchay Hospital, Bristol; Dr Sharon Saint Lamont, Head of Quality and Innovation, North East Strategic Health Authority; Dr Ian Lewin, Consultant Endocrinologist, North Devon District Hospital; Dr Anne McCune, Consultant Hepatologist, University Hospitals Bristol NHS Foundation Trust; Professor John McMurray, Professor of Medical Cardiology, University of Glasgow; Dr Mohit Misra, General Practitioner, Queen Elizabeth Hospital, London; Ms Sarah Parry, CNS Paediatric Pain Management, Bristol Royal Hospital for Children; Ms Pamela Rees, Lay Member; Dr Ann Richardson, Lay Member; Dr Paul Robinson, Medical Director, Merck Sharp & Dohme; Ms Ellen Rule, Programme Director, NHS Bristol; Mr Stephen Sharp, Senior Statistician, MRC Epidemiology Unit; Dr Peter Sims, General Practitioner, Devon; Dr Eldon Spackman, Research Fellow, Centre for Health Economics, University of York; Mr David Thomson, Lay Member; Dr John Watkins, Clinical Senior Lecturer, Cardiff University, Consultant in Public Health Medicine, National Public Health Service Wales; Dr Olivia Wu, Reader in Health Economics, University of Glasgow

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Edwards SJ, Karner C, Trevor N, Barton S, Nherera L. Mirabegron for the treatment of symptoms associated with overactive bladder: a single technology appraisal. London (UK): Biomedical Journals Technology Assessment Group (BMJ-TAG); 2013. 217 p. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Mirabegron for treating symptoms of overactive bladder. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. (Technology appraisal 290). Electronic copies: Available from the NICE Web site .
- NICE Pathways. Lower urinary tract symptoms in men overview. London (UK): National Institute for Care Excellence (NICE); 2013 Sep. Electronic copies: Available from the NICE Web site .
- NICE Pathways. Urinary incontinence in women overview. London (UK): National Institute for Care Excellence (NICE); 2013 Sept. Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Mirabegron for overactive bladder. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. 6 p. (Technology appraisal 290). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

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